UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,079	03/30/2004	Kalpana Kamath	01194-447001 / 02-160	5482

26161 7590 05/12/2009

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
PARVINI, PEGAH	
ART UNIT	PAPER NUMBER
1793	

NOTIFICATION DATE	DELIVERY MODE
05/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/814,079	KAMATH ET AL.	
	Examiner	Art Unit	
	PEGAH PARVINI	1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-13 and 21-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-13 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 4-8, 10-13 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,468,493 to Chevallier et al. in view of U.S. Patent Application Publication No. 2003/0206864 to Mangin.

Chevallier et al. teach porous silica particles or powders which are substantially spherical and preferably have an average size of at least 100 microns, for example, 220 microns or 215 microns (Abstract; column 4, lines 32-37; column 9, line 45; column 10, lines 52-55).

The disclosure of "at least 100 microns" is taken to have overlapping ranges with the ranges instantly claimed and overlapping ranges have been held to establish *prima facie* obviousness. MPEP § 2144.05.

Chevallier et al. disclose pore volume of between 175 and 275Aº (i.e. about 17.5 to 27.5 nm). The reference, further, discloses pore diameter of less than or equal to 400Aº (i.e. about 40 nm). It is to be noted that there is overlapping ranges of pore volume in the disclosed range with the one instantly claimed, and overlapping ranges have been held to establish *prima facie* obviousness. MPEP § 2144.05.

Furthermore, Chevallier et al. disclose that the pore volume of the pores with a diameter of between 100 to 300 Aº (i.e. about 10 to 300 nm) is at least 0.82 cm^3/g; the

reference, in an embodiment discloses that, for example, the pore volume represented by the pores of less than 400 Aº (i.e. about 40 nm) is about 1.03 cm^3/g (column 7, lines 35-38; column 9, lines 30-45; column 10, lines 40-53; column 11, lines 45-60).

Chevallier et al. do not expressly disclose the suspension of said silica particles in a carrier fluid.

Mangin, drawn to embolic particle dispersions, contrast agents and compositions suitable for affecting embolization or occlusion of a vessel or a duct which particles, agents and compositions are visible under ultrasound, teach the use of a compatible carrier fluid in said composition with the embolic particles and agents (Abstract; [0017]) wherein the compatible carrier fluid may be saline ([0063]). Mangin et al., additionally, disclose the use of silica particles as the embolic particles ([0015], [0026]) wherein the embolic particles comprise one or more voids ([0015]). Thus, although the reference may not literally disclose porous embolic particles, based on the disclosure above, it would have been obvious to have porous silica particles as the reference discloses silica particles as embolic particles having voids therein. Furthermore, the reference makes it obvious that the choice of particle size is on the basis of the size of the vessel to be occluded, the desired duration of occlusion, the type of abnormality to be treated, and is substantially commensurate with the desired microbubble size of the gas which fills the voids to make the embolic particles visible by ultrasound ([0003], [0047]). Additionally, Mangin teaches that the embolic particles may be used in a combination with drugs or toxins or with chemotherapeutic agents to increase the therapeutic value of the composition ([0067]). Moreover, Mangin teaches that the embolic particles are

immersed in a sterile physiological solution ([0063]). Finally, Mangin et al. disclose that the embolic particles may be of a wide variety of shapes such as spherical which is the most preferred shape ([0029]).

It would have been obvious to one of ordinary skill in the art to utilize the porous silica particles of Chevallier et al. in a composition comprising a contrast agent and a carrier fluid such as saline as that taught by Mangin motivated by the fact that it is known to use silica particles in compositions for affecting embolization as Mangin teaches that silica particles, with preferably spherical shape, with more than one voids therein are known in the art to be used in such compositions (Mangin, [0026]) wherein the size of said particles depends on a number of factors such as the size of the vessel to be occluded, the desired duration of occlusion, and the type of abnormality to be treated. Therefore, the use of porous silica particles in spherical shape is known in the art to be used in carrier fluids to be injected in the body with a contrast agent. The use of contrast agent, as known in the art and disclosed by Mangin, make is available to obtain ultrasound images of tissues and organs.

With further references to claims 10 and 11, it is to be noted that since the combination of references discloses porous silica particles in spherical shapes which have a particle diameter of a range that has overlapping ranges with the one instantly claimed and wherein said silica is also dispersed in saline, the properties or characteristics of loss of attrition resistance of about 0.1% by weight or less and a tolerance of about 10 nm or less on the mean pore diameter for 70% or more of the

pore volume in the pore volume distribution are expected to follow from the composition of the references as combined absence clear evidence showing the contrary.

It should be noted that it is well settled that when a claimed composition appears to be substantially the same as a composition disclosed in the prior art, the burden is properly upon the applicant to prove by way of tangible evidence that the prior art composition does not necessarily possess characteristics attributed to the claimed composition. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Circ. 1990); *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980); *In re Swinehart*, 439 F.2d 2109, 169 USPQ 226 (CCPA 1971).

With further references to claims 24 and 25, it is to be noted that, as detailed out above, the combination of references discloses porous silica particles in spherical shapes which have a particle diameter of a range that has overlapping ranges with the ones instantly claimed and wherein said silica is also dispersed in saline; thus, the properties of tolerance of pore diameter and loss of attrition resistance of the silica particles are assumed to be characteristics followed from the composition of the claims absence clear evidence showing the contrary. It should be noted that it is well settled that when a claimed composition appears to be substantially the same as a composition disclosed in the prior art, the burden is properly upon the applicant to prove by way of tangible evidence that the prior art composition does not necessarily possess characteristics attributed to the CLAIMED composition. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Circ. 1990); *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980); *In re Swinehart*, 439 F.2d 2109, 169 USPQ 226 (CCPA 1971).

Claims 4, 9 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,482,324 to Kirkland et al.

This is not a new rejection and is based on applicants amendments to claim 9 which defines the density. It is noted that claim 4 has been rejected since claim 9 depends on claim 4.

Kirkland et al. disclose porous silica microspheres contained in a reaction medium (i.e. carrier fluid) which have a particle size of 10 microns to 200 microns and have a density of at least 1.2 g/cc (Abstract; column 4, lines 57-63; column 10, lines 48-55, claims 1-2). Kirkland et al., further, disclose that said silica particles have a porosity of from about 50% to about 65% (column 5, lines 1-5); this is seen to have overlapping ranges with the instantly claimed pore volume when converted to ml/g absence clear evidence showing the contrary.

With reference to density and particle size, it is to be noted that overlapping ranges have been held to establish *prima facie* obviousness. MPEP § 2144.05.

With further references to claims 22 and 23, it is to be noted that, as detailed out above, Kirkland et al. disclose porous silica particles in spherical shapes which have a particle diameter of a range that has overlapping ranges with the one instantly claimed and wherein said silica is also contained in a medium (i.e. carrier fluid); thus, the properties of tolerance of pore diameter and loss of attrition resistance of the silica particles are assumed to be characteristics followed from the composition of the claims absence clear evidence showing the contrary. It should be noted that it is well settled

that when a claimed composition appears to be substantially the same as a composition disclosed in the prior art, the burden is properly upon the applicant to prove by way of tangible evidence that the prior art composition does not necessarily possess characteristics attributed to the CLAIMED composition. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Circ. 1990); *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980); *In re Swinehart*, 439 F.2d 2109, 169 USPQ 226 (CCPA 1971).

Response to Amendment

Applicants' amendment to claim 4, filed February 2, 2009 is acknowledged. However, said amendment does not place the application in condition for allowance.

Response to Arguments

Applicants' arguments filed February 2, 2009 have been fully considered but they are not persuasive.

Applicants have argued that Chevallier does not explicitly disclose that his silica particles have a pore volume of from about 0.4 ml/g to about 1.6 ml/g.

The Examiner, respectfully, submits that as detailed out previously and above, Chevallier et al., for example, disclose that the pore volume of the pores with a diameter of between 100 to 300 Aº (i.e. about 10 to 300 nm) is at least 0.82 cm^3/g; it should be noted that this pore volume has overlapping ranges with the pore volume instantly claimed, and overlapping ranges have been held to establish *prima facie* obviousness. MPEP § 2144.05.

Applicants have argued that neither Chevallier nor Mangin explicitly disclose that their particles have the indicated pore distribution (recitation of claim 10) and the loss of attrition resistance (recitation of claim 11); they, further argue that the Examiner provided no evidence to support the statement referring to said characteristics as properties.

The Examiner, respectfully, submits that, as noted previously and again above, since the combination of references discloses porous silica particles in spherical shapes which have a particle diameter of a range that has overlapping ranges with the one instantly claimed and wherein said silica is also dispersed in saline; thus, the properties of tolerance of pore diameter and loss of attrition resistance of the silica particles are assumed to be characteristics followed from the composition of the claims absence clear evidence showing the contrary. Applicants have not submitted any evidence proving that the porous silica of the combination of references as detailed out above can not have the characteristics recited in Applicants' claims 10 and 11.

Specifically, with reference to Applicants argument drawn to the point that the Examiner provided no evidence to support the statement referring to said characteristics as properties, it is well settled that when a claimed composition appears to be substantially the same as a composition disclosed in the prior art, the burden is properly upon the applicant to prove by way of tangible evidence that the prior art composition does not necessarily possess characteristics attributed to the CLAIMED composition. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Circ. 1990); *In re Fitzgerald*, 619 F.2d

67, 205 USPQ 594 (CCPA 1980); *In re Swinehart*, 439 F.2d 2109, 169 USPQ 226 (CCPA 1971).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEGAH PARVINI whose telephone number is (571)272-2639. The examiner can normally be reached on Monday to Friday 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pegah Parvini/
Examiner, Art Unit 1793

/Michael A Marcheschi/
Primary Examiner, Art Unit 1793